FEB 14 2013

SECTION 2	510(k) SUMMARY
510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
Submitter	PuriCore Inc. 508 Lapp Road Malvern, PA 19355
Contact Person	Art Morse Director of Quality Assurance and Regulatory Affairs PuriCore Inc. 508 Lapp Road Malvern, PA 19355 484 321 2728 (O), 484 321 2704 (F), 610 306 2870 (C)
Date Prepared	September 28th, 2012
Trade Name	Vashe® Wound Therapy Solution
Common Name	Wound Cleanser
Classification Name	Solution, Saline, (Wound Dressing)
Predicate Devices	Vashe® Wound Therapy System (including Vashe® Wound Therapy+ Solution); PuriCore Inc. K100918, August 9th, 2010
Modified Device Description	Vashe® Wound Therapy Solution is a wound cleanser solution that contains hypochlorous acid generated from sodium chloride solution through the proprietary electrochemical process. Hypochlorous acid acts as a preservative that inhibits microbial contamination within the solution. The device is presented as a prescription product that requires the practitioner to diagnose the disease state and prescribe the product.
Intended Use	Vashe® Wound Therapy Solution is intended for cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings. These indications are identical to the predicate device Vashe® Wound Therapy System (including Vashe® Wound Therapy+ Solution), K100918.
Summary of Technological Characteristics Compared to the Predicate Device	Vashe® Wound Therapy Solution similar to Vashe® Wound Therapy System (including Vashe® Wound Therapy+ Solution), K100918, includes among its labeled uses the cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings. The predicate device Vashe® Wound Therapy System (including Vashe® Wound Therapy+ Solution), K100918, produces Vashe® Wound Therapy Solution for intended use at the customer's location. The modified device, Vashe® Wound Therapy Solution, is produced by the Vashe® Production System in a validated manufacturing process at PuriCore Inc. Malvern, PA, bottled and distributed in bottles to customers. All other indications are identical. These differences are not critical because the intended use and the fundamental scientific technology are the same.

	PREDICATE DEVICES	MODIFIED DEVICE
	K100918 **Vashe® Wound Therapy System and Solution**	**Vashe® Wound Therapy Solution**
	Aqueous solution and electrochemical generator:	Aqueous solution:
Design Material	**Vashe® Wound Therapy Solution** (Produced from on-site **Vashe® Wound Therapy System)** to the following product specifications: • Available Free Chlorine (AFC) at 150 to 250 ppm • pH at 5.3 to 6.75ppm	**Vashe® Wound Therapy Solution** (Produced from central manufacturing, packaging, and distribution from PuriCore in Malvern, PA) to the following product specifications: • Upper specification expanded Available Free Chlorine (AFC) at 150 to 330 ppm • Lower specification expanded pH at 3.5 to 6.75ppm
Chemical Composition	Approximate percentages: Water 99.574% Sodium Chloride (0.4%) Hypochlorous Acid (0.025%) Sodium Chlorate (0.001%)	Approximate percentages: Water 99.574% Sodium Chloride (0.4%) Hypochlorous Acid (0.025%) Sodium Chlorate (0.001%)
	Wound Therapy Solution with Hypochlorous Acid as solution preservative	Wound Therapy Solution with Hypochlorous Acid as solution preservative
Energy Source	No Energy Requirements Aqueous Solution	No Energy Requirements Aqueous Solution
Substantial Equivalence - Effectiveness	The Modified Device utilizes the same fundamental scientific technology as the predicate devices. The only difference is the specification changes and place of production: at the Customer's Location (K100918) verses PuriCore in Malvern, PA (modified device). Non-Clinical equivalency testing was conducted for Shelf Life and Evaluated for Chemical Stability (See Section 6).	
Substantial Equivalence - Safety	Preservative effectiveness of hypochlorous acid at below minimal recommended concentration of hypochlorous acid Biocompatibility studies were conducted under verse case scenario, doubled initial concentration of available free chlorine relative to the beginning of shelf life, and reduced below minimal pH and doubled final concentration of available free chlorine relative to the end of shelf life (See Section 7)	
Test & Conclusion	Modifications to Vashe® Wound Therapy Solution has not changed the Intended Use or has not altered the Fundamental Scientific Technology of the predicate device; Vashe® Wound Therapy System (with Vashe® Wound Therapy® Solution) K100918.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Puricore, Incorporated
% Mr. Art Morse
Director of Quality Assurance and Regulatory Affairs
508 Lapp Road
Malvern, Pennsylvania 19355

February 14, 2013

Re: K123072
Trade/Device Name: Vashe® Wound Therapy Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 30, 2013
Received: January 31, 2013

Dear Mr. Morse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PuriCore
Pure Science. Pure Life.

K123072

Indications for Use Statement

510(k) Number:

Device Name: Vashe® Wound Therapy Solution

Indications for Use:

Vashe® Wound Therapy Solution is intended for cleansing, irrigating, moistening, and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin in addition to moistening and lubricating absorbent wound dressings.

Vashe® Wound Therapy Solution is intended for use by a qualified healthcare personnel trained in its use.

Prescription Use XX (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use: ____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDHR, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123072